K073526

510(k) Summary of Safety and Effectiveness - as required by 21 CFR part 807.92

Date prepared:	December 12 2007
Submitted by:	Amicas, Inc. 20, Guest St. Boston, MA 02135

MAR 12 2008

Contact:	Patrice Nedelec
Contact email:	pnedelec@amicas.com
Contact Telephone:	617-779-7858 or 617-372-1331
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Device Trade Name:	Amicas Vision Series PACS 5.5
Device Common Name:	Picture Archiving Communication System (PACS)
Regulation number:	892.2050
Device Classification:	Class II
Name:	Amicas Vision Series PACS
Predicate Device:	Amicas Vision Series PACS 4.3
Predicate Device Manufacturer:	AMICAS Inc. 20 Guest Street Boston, MA 021235
Predicate Device 510(k) number:	K062477
Date received:	08/24/2006
Decision date:	10/27/2006
Decision:	Substantially equivalent
Panel Code Device reviewed by:	Radiology
Panel Code Device classified by:	Radiology
Product Code:	LLZ
Regulation number:	892.2050
Device Classification:	Class II

Device Description and intended use:

AMICAS Vision Series PACS 5.5 is software intended to create and display two-dimensional and three-dimensional images of anatomy from a series of digitally acquired images.
Typical users of Vision PACS Series 5.5 are radiologists, technologists and clinicians.

Technological characteristics:

Feature	Amicas Vision Series PACS 4.3 (predicate)	Amicas Vision Series PACS 5.5
Software Only	Yes	Yes
Image Measurements	Yes	Yes
Multi-planar reformatting	Yes	Yes
Volume Rendering	Yes	Yes
Maximum Intensity Projection	Yes	Yes
Image editing	Yes	Yes
Printing	Yes	Yes
DICOM Images	Yes	Yes
Lossless JPEG2000 Compression	Yes	Yes
Lossy JPEG2000 Compression	Yes	Yes
DICOM Overlay supporting MQSA-requirements	Yes	Yes
Support for all DICOM transfer syntax and photometric interpretations	No	Yes

General Safety Considerations

Amicas Vision Series 5.5 software and the computer platform that it is installed on together constitute a system for the interpretation of medical image data by trained and qualified professionals. It is the user's responsibility to ensure that image quality, display quality, environmental lighting and other possible distractions are consistent with the clinical application. Refer to the instruction manuals for your specific computer and display hardware for information regarding installation, calibration and additional safety issues.

Amicas Vision Series 5.5, as its predicate, includes tools for enlarging, highlighting and obscuring portions of an image relative to other portions. Inappropriate application of these tools can result in the obscuration of important anatomy and contribute to an erroneous interpretation. It is the user's responsibility to understand the effect of image manipulation tools and to apply in a manner consistent with the clinical application. The user must review the cautionary statements in the User's guide.

Be sure to limit access to patient data to authorized individuals who are fully trained and qualified to use this equipment.

Testing:

Amicas Vision Series 5.5 is tested with reference to its Software Requirements Specifications, as documented in the Verification Procedure included in this 510(k) filing.
Functional testing is an integral part of Amicas, Inc. Product Development process, also included in this filing (see section G, Quality Procedure 0019).
The Amicas Quality Assurance Team, per process, independently verifies completeness of all deliverables -to include testing reports and assessment of safety and effectiveness- before issuing release advisories.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
9200 Corporate Blvd.
Rockville MD 20850

MAR 12 2008

Mr. Patrice J. C. Nedelec
Director of Quality
AMICAS, Incorporated
20 Guest Street
BOSTON MA 02135

Re: K073526
Trade/Device Name: AMICAS Vision Series PACS 5.5
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: December 13, 2007
Received: December 17, 2007

Dear Mr. Nedelec:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter.

21 CFR 876.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Nancy C Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K073524

Device Name: AMICAS Vision Series PACS 5.5

Indications For Use:

Vision Series PACS 5.5 is designed and marketed for soft copy reading, communication and storage of studies produced by digital modalities, to include Digital Mammography.

Vision Series PACS receives images acquired from DICOM-compliant medical imaging systems, data from FDA-cleared Computer-Aided Detection systems and other FDA-cleared Image processing systems.

Vision Series PACS imports images and render said images, upon request, within the AMICAS LightBeam Diagnostic Workstation utilizing both lossless (reversible) and lossy (irreversible) compression.

To support the diagnostic interpretation of Mammography studies, Vision Series PACS will display the full fidelity DICOM image in a non-compressed format. Images will be rendered with patient and clinical information clearly displayed as part of the DICOM Overlay as required by MQSA, on monitors cleared by FDA for use in Digital Mammography. Lossy compressed mammography images and digitized film screen images should not be used for the purpose of primary diagnosis. Mammographic images may only be interpreted using an FDA approved monitor that offers at least 5Mpixel resolution and meets other technical specifications reviewed and accepted by FDA.

Within Vision Series PACS 5.5, the AMICAS Real Time Worklist offers real-time status of radiology activity and provides customizable workflow management capabilities. Communication of critical results is facilitated and documented through optional, and configurable, components within the Real Time Worklist.

Vision Reach is an optional component within the PACS 5.5 offering which provides clinicians secure, proactive communication and access to clinical reports and images.

Order and Report information generated by HIS/RIS and report creation systems are received and displayed in PACS via the transmission of HL7 messaging. For this data, AMICAS is not the creator, but instead the downstream recipient which relies on the validity of data from said systems.

Vision Series PACS must be installed on suitable, commercial-standard hardware.

It is the user's responsibility to ensure monitor quality, ambient light conditions and image compression ratios are consistent with the clinical application.

PTO

Prescription Use ✓ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K073526